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EXAMINER

NAVARRO, A

ART UNIT

PAPER NUMBER

1645

16

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/292,437

Applicant(s)

Schneewind et al

Examiner

Mark Navarro

Group Art Unit

1645



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-97 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-97 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 26-29, and 49-54, drawn to a sortase-transamidase enzyme, classified in class 435, subclass 183.
 - II. Claims 8-25, drawn to nucleic acids encoding a sortase-transamidase enzyme, classified in class 536, subclass 23.1.
 - III. Claims 30-42, drawn to a method for screening a compound for anti-sortase-transamidase activity, classified in class 435, subclass 7.1.
 - IV. Claims 43-48, drawn to antibodies, classified in class 530, subclass 387.1.
 - V. Claims 55-61, drawn to a method for displaying a polypeptide on the surface of a Gram-positive bacterium, classified in class 435, subclass 69.1.
 - VI. Claims 62-65, drawn to a polypeptide displayed on the surface of a Gram-positive bacterium by covalent linkage, classified in class 530, subclass 300.
 - VII. Claim 66, drawn to a method for vaccination of an animal with a polypeptide, classified in class 424, subclass 184.1.
 - VIII. Claim 67, drawn to a method for vaccination of an animal with a covalent complex, classified in class 424, subclass 193.1.
 - IX. Claims 68-74, drawn to a method for screening for expression of a cloned polypeptide, classified in class 435, subclass 6.

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- X. Claims 75-78, drawn to a method for the diagnosis of a bacterial infection, classified in class 435, subclass 7.4.
- XI. Claims 79-83, drawn to a conjugate comprising an antibiotic and a protein, classified in class 530, subclass 350.
- XII. Claims 84-89, drawn to sortase-transamidase activity, classified in class 435, subclass 183.
- XIII. Claims 90-97, drawn to DNA encoding the proteins of Group XII, classified in class 536, subclass 23.1.

In the event that Applicant's elect group XII or XIII, Applicant's are further restricted to one sequence (i.e., SEQ ID NO: 4, 5, 6, 7, 8, 34, 35, or 36), for prosecution.

It is noted that Applicant's have elected group II, claims 8-25. However, as set forth in MPEP 803.04 nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions. SEQ ID NO: 3 (claim 8) encompasses multiple amino acid substitutions, and each of these substitutions results in the generation of a structurally distinct chemical compound, accordingly Applicant's are restricted to a single nucleotide sequence encoding one single protein. (i.e. SEQ ID NO: 3, or SEQ ID NO: 3 in which aspartate number 30 is glutamic acid, etc.)

- 2. The inventions are distinct, each from the other because of the following reasons:

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Invention I drawn to an enzyme, and Invention II drawn to nucleic acids are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention IV drawn to an antibody is distinct from Inventions I-III and V-XIII, since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing.

Invention III, drawn to a method for screening a compound for anti-sortase-transamidase activity is distinct from Inventions I-II and IV-XIII, since it requires additional biological reagents and parameters for the detection of the compound.

Invention V, drawn to method for displaying a polypeptide on the surface of a Gram-positive bacterium is distinct from Inventions I-IV and VI-XIII, since it requires additional biological reagents and parameters for the detection of the polypeptide on the surface of a bacterium.

Invention VI, drawn to a polypeptide displayed on the surface of a Gram-positive bacterium, is distinct from Inventions I-V and VII-XIII, since it requires the polypeptide to be displayed in a manner that is accessible to a ligand.

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Invention VII, drawn to a method of vaccination and Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used for vaccination as claimed or alternatively may be used in a method of diagnosis also as claimed.

Invention VIII, drawn to a method for vaccination is distinct from Inventions I-VII and IX-XIII since it requires vaccination with a covalent complex which has a separate biological activity and function.

Invention IX, drawn to a method for screening for expression of a cloned polypeptide, is distinct from Inventions I-VIII and X-XIII, since it requires additional biological reagents and parameters for the detection of the polypeptide.

Invention X, drawn to a method for the diagnosis of a bacterial infection is distinct from Inventions I-IX and XI-XIII, since it requires additional biological reagents and parameters for the detection of the bacterial infection.

Invention XI, drawn to a conjugate of an antibiotic and a protein is distinct from inventions I-X and XII-XIII, since it has a unique biological activity and function.

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Invention XII, drawn to a sortase-transamidase enzyme is distinct from Inventions I-XI and XIII, since they are all distinct proteins with distinct primary amino acid structures obtained from separate microorganisms.

Invention XIII, drawn to a DNA encoding a sortase-transamidase enzyme is distinct from Inventions I-XII, since they all encode distinct proteins with distinct primary amino acid structures obtained from separate microorganisms.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

March 12, 2001